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**Competitive Bidding for Clinical Lab Services:
Where's It Heading and What Small Businesses Can Expect
Hearing of the House Committee on Small Business
2360 Rayburn House Office Building
July 25, 2007**

My name is Tod Schild. I am the Senior Vice President of Shiel Medical Laboratory (“Shiel”) headquartered in the Brooklyn Navy Yard, which is part of the 12th Congressional District. I am testifying on behalf of our laboratory today, but I also wish to associate myself with the written testimony of the National Independent Laboratory Association (“NILA”), of which our laboratory is a member. Shiel is a commercial clinical laboratory employing 360 employees. 70 percent of our testing volume comes from physician practices, 25 percent from a total of 80 Nursing Homes and 5 percent from institutional accounts.

The demonstration project designed by the Centers for Medicare and Medicaid Services (“CMS”) will irrevocably alter the market for laboratory services, reduce patient choice, and limit access to quality testing.

The project has critical flaws and missing pieces. Rather than fostering competition it will create government sponsored oligopolies. Instead of reducing laboratory costs for Medicare, it will increase costs. Rather than improve the quality of healthcare, it will diminish patient access and stifle life-saving innovation. We all agree that overall Medicare cost reductions are desirable, but this is not an appropriate way to achieve that goal.

I. Structure of the Laboratory Market

In order to understand the impact of the proposed Medicare project, it is essential to understand the structure of the independent laboratory market. The Institute of Medicine highlighted this issue in its 2000 report, Medicare Laboratory Payment Policy. The report notes that:

Market consolidation has radically changed the face of the independent laboratory sector. Two companies, Quest Diagnostics and LabCorp, largely through mergers and acquisitions, [now] account for 61 percent of the testing conducted by independent laboratories.

NILA has updated the distribution of market shares and converted this data into a pie chart that appears as Attachment A. This chart dramatically illustrates the highly concentrated nature of the laboratory market. Two large laboratories now control over 65 percent of all independent laboratory testing. The remaining community laboratories continue to be locally viable and provide essential services, but they are particularly vulnerable when the playing field is not level. The competitive bidding demonstration designed by CMS could irrevocably shift the remaining market shares to the two dominant laboratories. The government should not further fuel the fire of market concentration. It should be investigating strategies to create a more diversified and competitive market.

In 2003, the Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) intervened in a merger between Quest and Unilab in California because of their concerns regarding market concentration and required Quest to divest a substantial number of patient service centers to maintain the competitive nature of the local independent laboratory market. Ironically, CMS may end up through this project creating the very type of dominant laboratory that the FTC and DOJ opposed.

II. Labs Will Shut Down, Jobs will be Lost

If the CMS proposal is allowed to proceed, hundreds of small and medium sized local and regional labs will shut down. Thousands of technical and non-technical jobs will be lost. This is not rhetoric. It is a fact. Medicare is a significant portion of the work most labs do. At Shiel Medical Lab, it is 30 to 33 percent. It is not uncommon for labs that focus primarily on nursing homes to have 70 to 80 percent Medicare. Furthermore, small and regional laboratories begin the bidding process on an uneven playing field. The two largest providers in the marketplace have the benefit of being able to shift their costs outside of the demonstration zone. The bid we submit will most likely be for all of our Medicare work. The large national laboratories can discount their bids in the demonstration zone and compensate for these temporary discounts through their work in other parts of the country.

Loss of the ability to perform and bill tests for Medicare patients would most assuredly be a death sentence for the vast majority of non-winning bidder laboratories. The way the demonstration was designed is that only a handful of laboratories will be winners in the demonstration area. Non-winners will be out of the program for three years before they get a chance to bid again. Very few will even be around at that point. I can illustrate this easily using Shiel as an example. Our profit margin, you may be surprised to know, is only between five and seven percent. If we were to lose 30 percent of our total revenue it would be difficult to keep our doors open for even a year, and impossible beyond that. The surviving labs will be the national giants. In lower New York, there are at least 30 labs that would be required bidders. Even if 10 were “winners” (which is unlikely) in the bid process, 20 quality labs will cease to exist. The whole concept of increasing competition that the demonstration hopes to accomplish simply disappears. Fewer players in the marketplace with higher demand for diminished services is the outcome. Over time, the simple economics of supply and demand comes into play, and we all know what the result of that is: higher costs.

III. What is a “Small Business Clinical Laboratory”?

Given that the demonstration project is fraught with danger for small community and regional clinical laboratories, it had been our hope that CMS would consult with the Small Business Administration (“SBA”) to determine how to define the term “small business” for purposes of this demonstration. Unfortunately, CMS did not do so.

CMS’s draft bidder’s package indicates that CMS has established \$100,000 in annual Medicare revenue as the outer limit for a small laboratory business that would be exempt from bidding. However, the SBA defines a “small business clinical laboratory” as one which has no more than \$12.5 million in annual overall revenue. Typically, small laboratories depend on Medicare for at least 40 percent of their revenues, which would mean that a small business laboratory might have as much as five million dollars in annual Medicare revenue, not \$100,000. CMS’s flawed definition of a small business lab therefore leaves many community clinical laboratories unduly exposed in the demonstration project.

IV. Small Business Laboratories Have Not Had a Real Voice in the Process

Not only does it appear that CMS did not consult with the SBA, the agency did not seek technical assistance from the small business laboratory community. At the beginning of the design phase, CMS established a Technical Expert Panel (“TEP”), selected by the agency to provide technical support for the demonstration project. While I understand the challenges of composing a panel with representation from all relevant sectors of the clinical laboratory community, I was disappointed that none of the selected TEP advisors represented the views of the truly local, independent community laboratory. Moreover, there was not a single non-physician laboratory director on the TEP. Given these facts, at the end of 2004, NILA sent a letter to CMS requesting that the agency consider adding one or more additional representatives to the TEP to ensure that the panel reflected the full range of clinical laboratory stakeholders. Unfortunately, the agency did not do so.

V. Result: More Market Concentration and Less Competition

It is my fear that CMS’s lack of consultation with the SBA and the small business laboratory community now leaves community and regional labs in a particularly vulnerable position in a demonstration project that already promises to leave in its wake a less competitive marketplace. The independent laboratory market, while still competitive, is highly concentrated. The two largest laboratories control more than 65 percent of that market. A poorly designed project will further reduce competition in the communities selected. It is unclear which steps, if any, that CMS has taken to ensure that the net result of this process will not be government-sanctioned oligopolies, duopolies, or monopolies.

In addition, I should note that the large national laboratories have substantially more assets than community and regional laboratories. From reviewing CMS’s draft design, I cannot see anything that would prevent the large national labs from using the demonstration as a mechanism to pick up market share. While CMS acknowledges the issue, the agency does not explain how it would take care of this serious potential problem. The agency allowed almost two years to pass between the two Open Door Forums on this issue, yet it still it could not answer this basic question. As someone whose livelihood depends on the survival of community and regional labs, I found this to be extremely frustrating.

**VI. Choice of Quality Laboratories will be Limited.
Service and Quality Levels will Deteriorate.**

Given that there will be fewer laboratories in the demonstration area, the number of walk-in patient service centers will be reduced. Currently, the two largest national labs have overcrowding in most of the Patient Service Centers. One of them has even gone to appointment scheduling, where if you walk in without an appointment the scheduled patients get priority. I have repeatedly heard of patients waiting one and two hours to get their blood drawn at some PSCs. Smaller lab PSCs pick up the slack. We are like a breath of fresh air to patients. I maintain an office in one of our PSCs, and I routinely have patients praise us for our quick service. Bear in mind they have already visited their physician and probably had to wait varying lengths of time for that visit. The last thing they want is to take their laboratory testing prescription and have to wait long periods again that same day, or the next morning if a fasting specimen is required. This does not just affect Medicare patients.

A serious patient care issue also will arise out of the mass closing of laboratories, and that is "continuity of care". Many of the same tests can use different methodologies and varying reference ranges from lab to lab. Physicians treating patients for acute and/or chronic illnesses will be forced to adapt to a different labs method, and it does not always transcend well. This is true particularly in the case of tumor marker tests for cancer patients. Even when we get a new account from one of our competitors, they will often not switch all of their patients because of the importance of continuity of care. A demonstration design that results in mass laboratory attrition from the Medicare program is a poorly designed and dangerous demonstration.

Then there are the physicians. Currently, all laboratories compete on quality and service. That is why community-based laboratories have flourished. There is a level of service that many physicians seek that, in their experience, is provided by smaller businesses. The forced closing of labs will affect the ability of a physician and patient to choose a quality lab of their choice. There will be a severe lack of access for all.

Another critical point to consider is the stifling of innovation. Many of the groundbreaking, life-saving tests have been developed by small laboratories. Exclusion from Medicare equals forced lab closures; which equal less access; which equals reduction of quality and test turnaround time due to overloading of the "winning" labs; which equals fewer resources and/or businesses that can be devoted to research and development. The domino effect that would occur in this scenario has to be avoided at all costs.

CMS might say that "capacity" of a lab to run each of the tests on the bid list will assure there is ample coverage in an MSA. However, the agency is depending on the bidding labs to accurately reflect their stated capacity for each test, and then CMS will go over by some margin to assure ample coverage. All of us in the industry see the fatal flaw in this approach. Estimated capacity is not a commitment. Laboratories may overstate their ability to service the market. While a distant

laboratory may have the ability to process tests, it might not have the infrastructure or local resources to maintain the same level of service with regard to the collection or processing of the specimens. A distant laboratory will simply not be available if our transportation systems become impaired due to natural disasters such as hurricanes or terrorist attacks such as September 11th.

VII. Nursing Home Hardship

Only local and regional labs service nursing homes. The large national laboratories long ago opted out of this market. The high cost of sending in personnel to draw blood and deliver results within several hours, and the limited Medicare reimbursement for on-site services and travel, have driven many labs to seek high profit margins elsewhere. Medicare competitive bidding will eliminate the existence of many of the labs that are willing to take on the high operating costs to provide quality care for our aging population in long-term care facilities. The large labs have admitted that this is not a population that they want to service. CMS implied that this will be a provision of “winner” participation in Medicare. Again, service levels will deteriorate. Inexperienced labs will have to institute nursing home coverage. The health monitoring requirements of the neediest segment of the U.S. population will suffer, and lives will be lost as a result of inadequate nursing home coverage. This is a fact. Delayed results, resulting in delayed medication, could seriously compromise patient care. Nursing home coverage is largely overlooked in the project design and is a major oversight by the authors of the bid process. Others testifying today will be able to provide greater detail regarding the substantial risk this project presents to nursing home patients - the most vulnerable segment of the Medicare population.

VIII. Demonstration Rigged Against Community and Regional Laboratories

The Medicare Competitive Bidding Demonstration discriminates mostly against small and medium sized laboratories operating in a few, or only one, Metropolitan Statistical Area (“MSA”). A national lab may be excluded from one or more MSAs, and it will have some financial impact on them; but a local lab that is excluded from Medicare in the single MSA in which it operates will have to cease all operations. Medicare competitive bidding for laboratories is the opposite of what it portends to be. It is clearly “Anti-Competitive.”

Medicare competitive bidding will irrevocably alter the market of any MSA that has the misfortune of being chosen. Long time quality laboratories will be forced out of business, and new start-up laboratories will be a thing of the past. The only type of new lab that would be able to open would be institutional labs that do employee drug testing, or labs that do not do direct patient or insurance billing. I would never have imagined a demonstration project that would make it impossible for a new full-service laboratory to enter the market place, and yet it seems to be happening.

IX. Demonstration Complexities and Unaddressed Aspects of the Program

The design complexity of the bidding process and the reporting to CMS required of winning lab bidders will require a large investment in personnel and infrastructure, potentially making it cost prohibitive for even the “winners” of the bid process. CMS significantly underestimates the time and cost of completing the forms. Laboratories will have to assess whether the facility is required to bid based on Medicare revenue from the previous year; assemble a complete financial statement; negotiate subcontractor arrangements with other laboratories and provide signed agreements; and determine capacity and bid price for almost every test on the clinical laboratory fee schedule. Moreover, the individuals needed to complete the forms would include those responsible for billing, collections, operations, and legal counsel. The hourly rates for these individuals are not being fully accounted for in calculating the financial burden on laboratories posed by this demonstration project.

In conclusion, there are no laboratory “winners” in the Medicare Competitive Bidding Demonstration, only “losers” and “bigger losers.” Our industry and the American public will be worse off, and no savings will result. The only result will be diminished quality, diminished access, diminished innovation, lost jobs, poorer health, lost lives, and further crippling of our already crippled national health care system. On behalf of the 360 employees of Shiel Medical Laboratory, NILA, our industry as a whole, and the citizens of the United States, we urge Congress to repeal Section 302(b) of the Medicare Modernization Act of 2003 that requires CMS to conduct a demonstration of Medicare Competitive Bidding for Part B Fee Schedule Clinical Laboratory Services.